

# PRODUCT INFORMATION

## Vinyl Isolator Sleeve

For cytostatic and biological agents

### Application and properties

- + **Maximum protection:** For maximum safety when working with CMR<sup>1)</sup> drugs (e.g. cytostatics) on isolators.
- + **Application range:** Use for isolators with a round shoulder ring with a diameter of 30 cm and in pharmaceutical work areas or when handling biological agents.
- + **Protective barrier:** Two-piece design - outer layer of laminated PVC HF and inner layer of knitted polyamide fabric with a flame-retardant and antimicrobial polyurethane coating for greater comfort, no sticking of the arm sleeves to the user's arm, welded seams. Integrated nitrile O-rings at both openings.
- + **Fastening instructions:** Check that it is properly attached to the isolator before use. Keep away from flames and heat sources.
- + **Replacement interval:** Depending on application, between 4 and 6 months.
- + **Before use:** Check for damage! Do not use damaged vinyl isolator arm sleeves!
- + **Disposal:** Waste requiring supervision (waste code: 18 01 04 according to 2000/532/EC), in case of heavy contamination waste requiring special supervision<sup>2)</sup> (waste code: 18 01 08\*<sup>3)</sup> or AS 18 01 03\*<sup>4)</sup> according to 2000/532/EC; collect and dispose of separately!

<sup>1)</sup>: Carcinogenic. Mutagenic. Toxic for reproduction. <sup>2)</sup>: Waste types marked with (\*) in the waste list are hazardous waste according to § 41 of the KrW-/AbfG. <sup>3)</sup>: Cytotoxic and cytostatic drugs. <sup>4)</sup>: Waste whose collection and disposal is subject to special requirements from an infection prevention perspective.



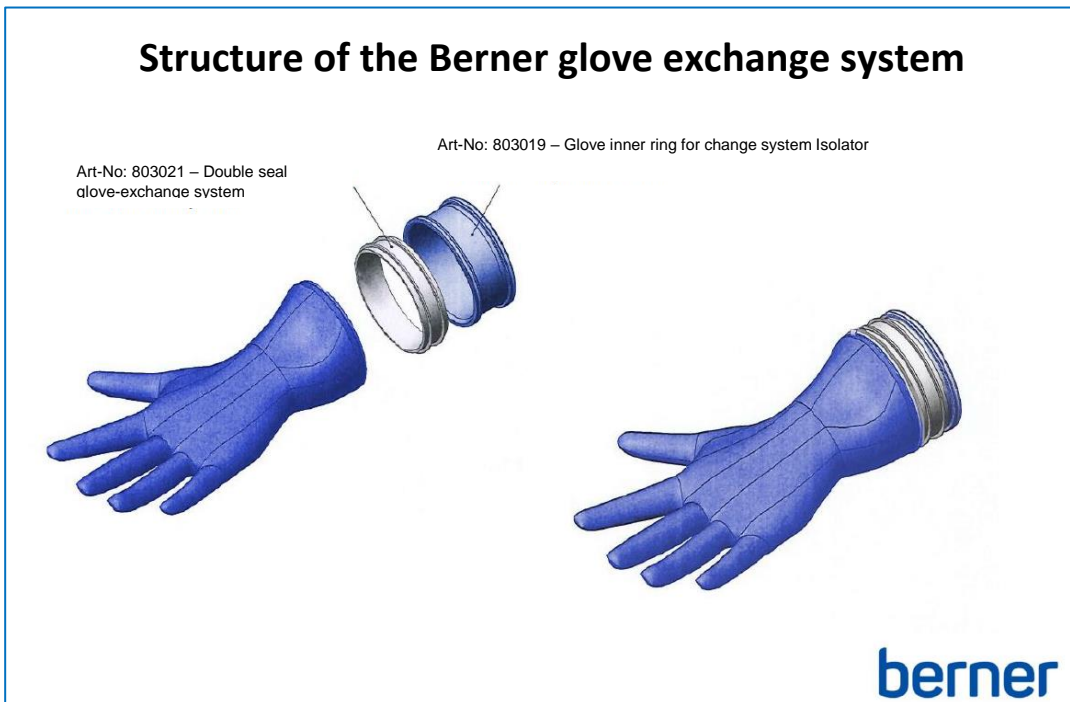
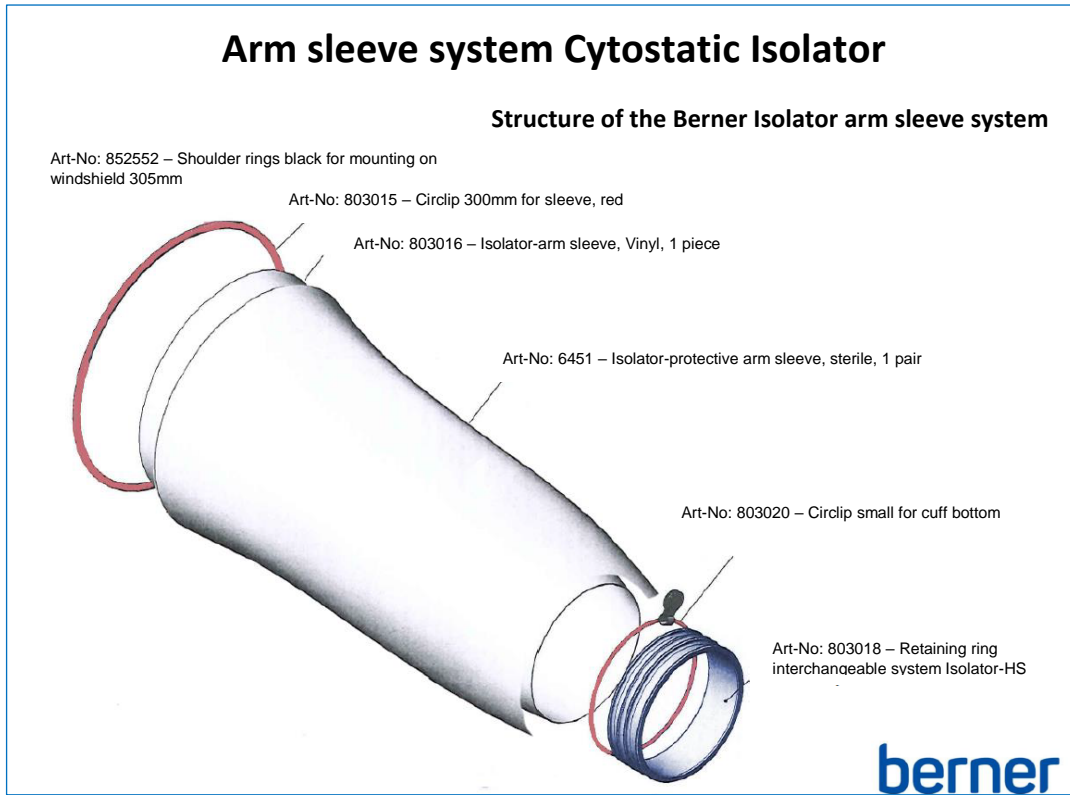
### Design

|           |                               |
|-----------|-------------------------------|
| Item-No.: | 803016                        |
| Size      | Uni                           |
| Length    | 510 mm ± 10 mm                |
| Width     | 300 mm (disc) / 120 mm (ring) |
| Quantity  | 1 piece                       |

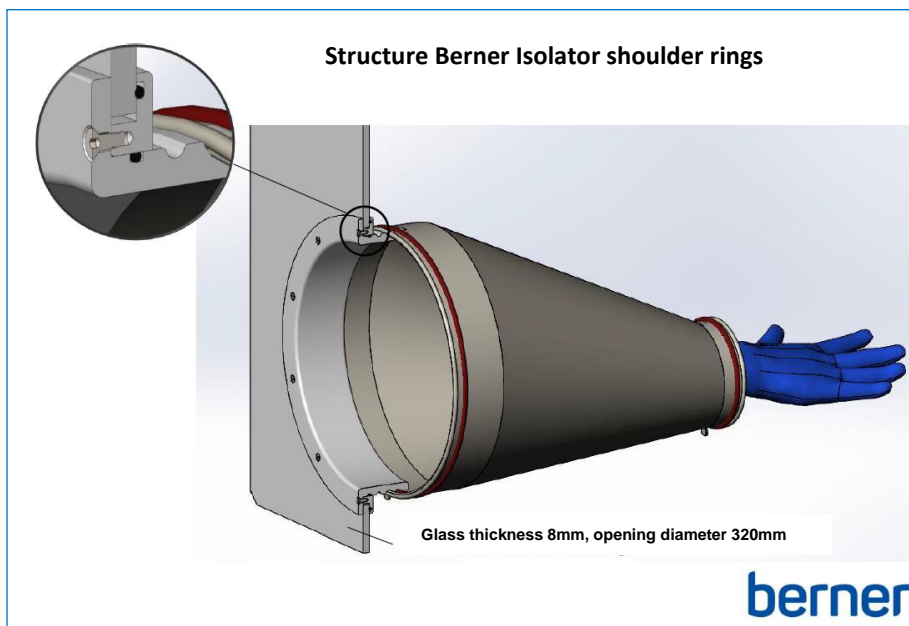
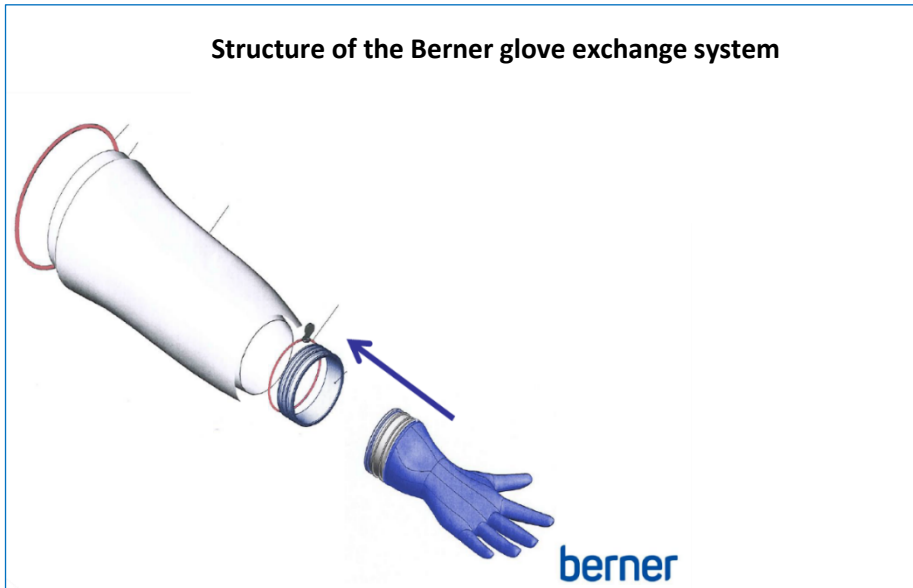
### Material

|                 |  |
|-----------------|--|
| Color           | White  |
| Outer coat      | Polyvinylchloride HF                                 |
| Inner coat      | Knitted polyamide coated with a polyurethane coating |
| Specific weight | 1,25 g/cm <sup>2</sup>                               |
| Total Mass      | 220 g/m <sup>2</sup>                                 |

## Composition of the arm sleeve system



## Structure of the glove system



## Article overview of the arm sleeve system

| Article Number | Description   |
|----------------|---|
| 852552         | Shoulder rings, black, for attachment to washer 305mm |
| 803015         | Circlip 300mm for cuff, red                           |
| 803016         | Isolator arm cuff, vinyl, 1 piece                     |
| 6451           | Isolator protective arm cuffs, sterile                |
| 803018         | Isolator-HS interchangeable system retaining ring     |
| 803019         | Inner glove ring for Isolator interchangeable system  |
| 803020         | Small retaining ring for lower cuff                   |
| 803021         | Double seal HS exchange system                        |

## Protection against chemical hazards

Permeation<sup>5)</sup> tested in accordance with the binding European standard EN 16523-1:2015. The breakthrough times<sup>6)</sup> [min] / performance classes<sup>7)</sup> (1-6) were determined for the following chemicals:

| Tested chemicals            | Breakthrough time [min] | Performance class |
|-----------------------------|-------------------------|-------------------|
| 5-Fluorouracil (10 mg/ml)   | > 480 min               | 6                 |
| Carmustine (3,3 mg/ml)      | > 480 min               | 6                 |
| Cisplatin (1 mg/ml)         | > 480 min               | 6                 |
| Cyclophosphamide (20 mg/ml) | > 480 min               | 6                 |
| Etoposide (20 mg/ml)        | > 480 min               | 6                 |
| Gemcitabine (40 mg/ml)      | > 480 min               | 6                 |
| ThioTEPA (10 mg/ml)         | > 480 min               | 6                 |

<sup>5)</sup>: Movement of a chemical through a material at the molecular level. <sup>6)</sup>: At a permeation rate of  $1\mu\text{g}/\text{min}\cdot\text{cm}^2$ , <sup>7)</sup>: The performance class does not reflect the actual duration of protection at the workplace!

## Care instructions

Wipe with a mild detergent. Do not use organic or phenolic-based cleaning agents. Wash by hand or dry clean with a cleaning agent up to 75 °C. For disinfection, use sodium hypochlorite with no more than 1.000 ppm active chlorine. Clean and dry completely before storage. Some surface creases may occur.

## Storage and transport conditions

- + Dark (protect from direct UV and sunlight)
- + Cold/Cool (+ 5 °C bis + 40 °C)
- + Dry (relative humidity 30 % - 60 %)
- + No contact with pointed and/or sharp objects

## Shelf life

Packaged version: In compliance with storage and transportation conditions, 3 years from production date in the original sterile packaging.

## Manufacturer

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